510(k) SUMMARY

K100207

FEB 12 2010

510(k) Owner:

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Date: November 2, 2009

Trade Name: NON-MYDRIATIC RETINAL CAMERA TRC-NW8F

Common names: Retinal Camera

Classification Name: Camera, Ophthalmic, AC-Powered
21CFR886.1120

Product Code: HKI

Identification of a Legally Marketed Predicate Device

The TRC-NW8F is substantially equivalent to the TRC-NW7SF MARKII (K090115), KOWA VX-10 (K043213) and TRC-NW200 (K041367). All of those predicate have same FDA Product Code HKI.

General Description

This product is a retinal camera designed to observe, photograph or record the fundus oculi of a patient without coming into contact with the patient's eye and provide as an electronic image the obtained fundus oculi information for subsequent diagnosis.

This product can take both color photography and fluorescein angiography.

This product is equipped with an observation monitor used for observation purpose and display of a photographed image. This product uses attached commercial digital single-lens reflex camera to photograph or record the fundus oculi of a patient.

A photographed image may be recorded on a commercial memory card built into an commercial digital single-lens reflex camera or a personal computer (hereinafter referred to as a PC) or commercial memory devices (flash memories, hard disc, etc.).

A commercial digital printer is connected and can print the observed images and the photographed images of the fundus.

Intended Use / Indication for Use

The NON-MYDRIATIC RETINAL CAMERA TRC-NW8F is intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, with the use of a mydriatic or without use of a mydriatic.

Patient Profiles

This instrument has not been designed to apply to infants. Use this instrument meticulously for infants.

This instrument is contraindicated in the following patients.

- The patient who has a history of photosensitivity.
- The patient who has just received the treatment of photodynamic therapy (PDT) (For the prohibition period, refer to the package insert of the taken light-sensitive substance.
- The patient who takes the medicine that can cause the photosensitivity as its side effect.

Use this instrument meticulously for the following patients.

- The patient who has epidemic kerato conjunctivitis, or any other infectious disease.
- The patient who has taken the medicine that can cause the photosensitivity as its side effect.
- The patient who is at high risk for the optical radiation hazard, such as aphakic eye, infant, and the patient who diminishes the sensibility to light by fundus disease.

Performance Data

The maximum exposure has been demonstrated to be well below the accepted threshold limits set out in ISO 15004-2:2007. (See Attachment 3)

The resolving power and the photographic angular field of view as defined in ISO 10940:1998 "Ophthalmic instruments -- Fundus cameras" have been measured and the result meet the requirement value set out in TOPCON self standards. (See Attachment 5)

In all instances, the NON-MYDRIATIC RETINAL CAMERA TRC-NW8F functioned as intended.

Basis of Substantial Equivalence

The TOPCON NON-MYDRIATIC RETINAL CAMERA TRC-NW8F is as safe and effective as TOPCON TRC-NW7SF MARKII (K090115), KOWA VX-10 (K043213) and TOPCON TRC-NW200 (K041367). The NON-MYDRIATIC RETINAL CAMERA TRC-NW8F and the predicated devices have the same intended use and similar indications, technological characteristics, and principles of operation. The minor technological differences between the NON-MYDRIATIC RETINAL CAMERA TRC-NW8F and its predicate devices raise no new issue of safety or effectiveness. Performance data demonstrate that the NON-MYDRIATIC RETINAL CAMERA TRC-NW8F is as safe and effectiveness as required in applicable international standards such as ISO 15004-2:2007 and so on. Thus, the NON-MYDRIATIC RETINAL CAMERA TRC-NW8F is substantially equivalent.

Standards for testing

TOPCON conducted several tests for the TOPCON Retinal Camera TRC-NW7SF MARK II to ascertain conformity to following standards.

IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991; Amendment 2, 1995
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, Edition 3:2007

ISO 15004-1:2006	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
ISO 15004-2:2007	Ophthalmic Instruments - Fundamental requirements and test methods Part 2: Light hazard protection

No deviation or adaptation is made in the use of above mentioned standards.
See Attachment 1 for IEC 60601-1 Test Reports and IEC 60601-1-2 Test Reports.
See Attachment 2 for ISO 15004-1:2006 Test Reports.
See Attachment 3 for ISO 15004-2:2007 Test Reports.
See Attachment 4 for Form FDA 3654 of each standard.

The NON-MYDRIATIC RETINAL CAMERA TRC-NW8F has no component which contacts with blood, bodily fluid or mucous membrane. Therefore, Biocompatibility tests were not performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Topcon Corp.
c/o Mr. Stefan Preiss
TUV SUD America Inc
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

FEB 12 2010

Re: K100207
Trade/Device Name: Non-Mydriatic Retinal Camera TRC-NW8F
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera, AC-Powered
Regulatory Class: Class II
Product Code: HKI
Dated: January 22, 2010
Received: January 25, 2010

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jessica Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100207

Device Name: NON-MYDRIATIC RETINAL CAMERA TRC-NW8F

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE ---- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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